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June 6, 2005

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Art Unit 1635

INTERNET ADDRESS: ESTEFFE@SKGF.COM

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Application No. 10/725,015; Filed: December 2, 2003

or: Method for Producing Sterile Polynucleotide Based Medicaments

Inventors:

GEALL et al.

Our Ref:

1530.0610001/EKS/J-H

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. SKGF Cover Letter;
- 2. Information Disclosure Statement under 37 C.F.R. § 1.97(b);
- 3. Form PTO-1449, 3 pages, listing 40 documents (AA1-AE3, AL1-AM2 and AR1-AT2);
- 4. One (1) copy of the 13 cited documents (AL1-AM2 and AR1-AT2); and
- 5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

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Commissioner for Patents June 6, 2005 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Eric K. Steffe

Attorney for Applicants Registration No. 36,688

EKS/J-H/tis:awt

368358v1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Confirmation No.: 3181

Geall et al.

Art Unit:

1635

Appl. No.: 10/725,015

Examiner:

Schnizer, R. A.

Filed: December 2, 2003

Atty. Docket: 1530.0610001/EKS/J-H

**Method for Producing Sterile** 

**Polynucleotide Based** 

**Medicaments** 

Information Disclosure Statement Under 37 C.F.R. § 1.97(b)

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents, AL1 to AM2 and AR1 to AT2 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, documents AA1 to AD3, cited on the attached Form PTO-1449 are not submitted.

The Examiner's attention is directed to the following co-pending, related applications:

U.S. Application No. 09/839,574, inventors Manthorpe et al., filed April 23, 2001, now published as U.S. Publication No. 2002/0019358 A1 (Document AI2)

U.S. Application No. 10/202,858, inventors Felgner et al., filed July 26, 2002, now published as U.S. Publication No. 2003/0032615 A1 (Document AJ2);

- U.S. Application No. 10/360,645, inventors Wolff *et al.*, filed February 10, 2003, now published as U.S. Publication No. 2003/0186913 A1 (Document **AK2**);
- U.S. Application No. 10/391,216, inventor Wheeler, C.J., filed March 19, 2003, now published as U.S. Publication No. 2003/0191082 A1 (Document AC2);
- U.S. Application No. 10/127,683, inventors Hobart et al., filed April 23, 2002, now published as U.S. Publication No. 2003/0203863 A1 (Document AD2);
- U.S. Application No. 10/725,009, inventor Geall, A., filed December 2, 2003, now published as U.S. Publication No. 2004/0157789 A1 (Document **AE2**);
- U.S. Application No. 10/748,853, inventor Wheeler, C.J., filed December 30, 2003, now published as U.S. Publication No. 2004/0171572 A1 (Document AF2);
- U.S. Application No. 10/738,986, inventors Hermanson *et al.*, filed December 19, 2003, now published as U.S. Publication No. 2004/0209241 A1 (Document **AG2**);
- U.S. Application No. 09/937,604, inventor Wheeler, C.J., which is the U.S. National Phase of International Appl. No. PCT/US00/08282 (WIPO Publication No. 00/57917 A2) (Document AL2), having a 35 U.S.C. §371 date of September 26, 2001;
- U.S. Application No. 09/478,457, inventors Wolff et al., filed January 6, 2000, now pending (Document AS2);
- U.S. Application No. 10/658,688, inventor Hermanson, G.G., filed September 10, 2003, now pending;

U.S. Application No. 10/843,656, inventors Vilalta et al., filed May 12, 2004, now pending;

U.S. Application No. 60/571,854, inventors Luke et al., filed May 18, 2004, now pending; and

U.S. Application No. 60/632,612, inventor Geall A., filed December 3, 2004, now pending;

which are directed to related technical subject matter. Copies of co-pending U.S. Application Nos: 10/658,688, 10/843,656, 60/571,854 and 60/632,612 are not provided pursuant to the Waiver of Requirements in 37 C.F.R. § 1.98, Official Gazette, October 16, 2004. A copy of co-pending U.S. Application No. 09/478,457 is provided as the application is not available electronically via the United States Patent and Trademark Office Image File Wrapper System (IFW). The identification of these U.S. Patent Applications is not to be construed as a waiver if secrecy as to those applications now or upon issuance of the present application as a patent.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits that document AT1 is in a foreign language. The relevance of document AT1 may be found in the English language abstract included therein.

The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the

effective U.S. filing date and any foreign priority date so that the month of publication is not

in issue. Applicants have listed publication dates on the attached PTO-1449 based on

information presently available to the undersigned. However, the listed publication dates

should not be construed as an admission that the information was actually published on the

date indicated.

Applicants reserve the right to establish the patentability of the claimed invention

over any of the information provided herewith, and/or to prove that this information may not

be prior art, and/or to prove that this information may not be enabling for the teachings

purportedly offered.

This statement should not be construed as a representation that a search has been

made, or that information more material to the examination of the present patent application

does not exist. The Examiner is specifically requested not to rely solely on the material

submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first

Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed

Form PTO-1449, and indicate in the official file wrapper of this patent application that the

documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSJER, GOLDSTEIN & FOX P.L.L.C.

Erio K. Steffe

Attorney for Applicants Registration No. 36,688

Date:

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Page 1 of 3 JUH 0 6 2005 TTY. DOCKET NO. APPLICATION NO. 530.0610001/EKS/J-H 10/725,015 **FORM PTO-1449** IRST NAMED INVENTOR Geall et al. INFORMATION DISCLOSURE STA FILING DATE ART UNIT December 2, 2003 1635 **U.S. PATENT DOCUMENTS EXAMINER** DOCUMENT NUMBER INITIAL DATE NAME CLASS SUB-CLASS FILING DATE AA1 5,264,618 11/23/1993 Felgner et al. 04/16/1991 AB1 5.459.127 10/17/1995 Felgner et al. 09/16/1993 AC1 5,567,859 10/22/1996 Emanuele et al. 08/09/1994 AD1 5,656,611 08/12/1997 Kabanov et al. 11/18/1984 AE1 5,674,911 10/07/1997 Emanuele et al. 06/06/1995 AF1 5,696,298 12/09/1997 Emanuele et al. 06/02/1995 AG1 5,990,241 11/23/1999 Emanuele et al. 07/08/1997 AH1 6.359.054 B1 03/19/2002 Lemieux et al. 01/08/1999 AI1 6,586,409 B1 07/01/2003 Wheeler 03/24/2000 AJ1 6,147,055 11/14/2000 Hobart et al. 03/14/1997 AK1 5,703,055 12/30/1997 Felgner et al. 01/26/1994 **FOREIGN PATENT DOCUMENTS** EXAMINER DOCUMENT INITIAL NUMBER DATE COUNTRY CLASS SUB-CLASS **TRANSLATION** Yes AL1 WO 96/04392 A2 | 02/15/1996 **WIPO** No Yes AM1 WO 96/04932 A1 | 02/22/1996 **WIPO** No Yes AN1 WO 97/40839 A1 | 11/06/1997 **WIPO** No Yes A01 WO 99/06055 A1 02/11/1999 **WIPO** No Yes AP1 WO 99/21591 A1 | 05/06/1999 **WIPO** No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Newman, M.J., et al., "Use of Nonionic Block Copolymers in Vaccines and Therapeutics," Crit. Rev. Ther. Drug Carrier Syst. 15:89-142, Begell House, Inc. (1998) AR 1 Todd, C.W., et al., "Systematic Development of a Block Copolymer Adjuvant for Trivalent Influenza Virus Vaccine," Dev. Biol. Stand. 92341-351, Karger (1998) AS 1 Tse, C. and Capeau, J., "Quantification des acides nucléiques par PCR quantitative en temps réel," Ann. Biol. Clin. 61:279-293, John Libbet Eurotext (May-June 2003) AT 1 **EXAMINER** DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

		Page 2 of 3
ATTY, DOCKET NO.	APPLICATION NO.	
1530.0610001/EKS/J-H	10/725,015	
FIRST NAMED INVENTOR		
Geall et al.		
FILING DATE	ART UNIT	
December 2, 2003	1635	

		56611		U.S. P	ATENT DOCUMENTS				
EXAMINER INITIAL		DOCU NUMB		DATE	NAME	CLASS	SUB-CLASS	FILING DATE	
	AA2	6,670,		12/30/2003	Wheeler			06/05/98	
	AB2	6,399,	588 B1	06/04/2002	Hobart et al.			07/28/2000	
	AC2	2003/0	)191082 A1	10/09/2003	Wheeler			03/19/2003	
	AD2	2003/0	203863 A1	10/30/2003	Hobart <i>et al</i> .			04/23/2002	
	AE2	2004/0	)157789 A1	08/12/2004	Geall			12/02/2003	
	AF2	2004/0	0171572 A1	09/02/2004	Wheeler			12/30/2003	
	AG2	2004/0	)209241 A1	10/21/2004	Hermanson et al.			12/19/2003	
	AH2	RE 36	,665	04/18/2000	Emanuele et al.			06/02/1998	
	Al2	2002/0	0019358 A1	02/14/2002	Manthorpe et al.			04/23/2001	
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	AK2	2003/0	0186913 A1	10/02/2003	Wolff et al.			02/10/2003	
	1			FOREIGN	PATENT DOCUMENT	S			
EXAMINER NITIAL		I	CUMENT MBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
	AL2	wo	0 00/57917 A2	10/05/2000	WIPO			Ye: No	
•	AM2	2 wc	0 02/00844 A2	01/03/2002	WIPO			Ye: No	
	AN							Ye N	
	AO							Ye:	
	AP							Ye N	
			OTHER (I	ncluding Aut	hor, Title, Date, Pertine	ent Pages, etc.	)		
	AR	2	"Cetrimide	," in: <i>Handboo</i>	I., eds., "Benzalkonium <i>k of Pharmaceutical Exc</i> , DC, pp.27-31, 96-98 (*	<i>cipients</i> , Americ	zethonium Ch can Pharmace	loride," utical	
				f Co-Pending U.S, Patent Application No. 09/478,457, Wolff et al., filed January 6, NOT PUBLISHED)					
	АТ	2	Todd, C.W., et al., "Development of an adjuvant-active nonionic block copolymer for use in oil-free subunit vaccines formulations," <i>Vaccine 15</i> :564-570, Elsevier Science Ltd. (1997)						
EXAMINER			<u> </u>			DATE	CONSIDERED	)	

## FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT

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	ATTY, DOCKET NO.	APPLICATION NO.	
	1530.0610001/EKS/J-H	10/725,015	
	FIRST NAMED INVENTOR		
	Geall et al.		
	FILING DATE	ART UNIT	
	December 2, 2003	1635	

EXAMINER	T	DOCUMENT	U.S. I	PATENT DOCUMENTS	1		
NITIAL		NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3	6,482,518 B1	11/19/02	Short et al.			07/30/1999
	AB3	5,994,314	11/30/1999	Wheeler			04/09/1996
	AC3	6,251,599 B1	06/26/2001	Chen et al.			11/06/1998
	AD3	5,691,387	11/25/1997	Emanuele et al.			06/03/1996
	AE3	6,867,195 B1	03/15/2005	Felgner et al.			06/07/1995
	AF						
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EXAMINER NITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
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	AO						Ye N
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